

ITW

141-446

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT OPERATION

In re Application of:

**Kositprapa et al.**

Serial No.: **10/777,542**

Group Art Unit: --

Filed: **February 12, 2004**

Examiner: --

**For: NOVEL PHARMACEUTICAL FORMULATION CONTAINING A BIGUANIDE  
AND A THIAZOLIDINEDIONE DERIVATIVE**

New York, NY 10036  
May 12, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

The following statement of relevance is submitted with the accompanying  
Form PTO/SB/08A.

Document  
Designation  
AA  
U.S.P. 3,174,901

Relevance  
Relates to a process for the oral treatment of diabetes.

AB  
U.S.P. 3,960,949

Relates to 1,2-biguanides.

AC  
U.S.P. 4,166,800

Relates to a process for preparation of microspheres.

I hereby certify that this correspondence is being deposited with the  
United States Postal Service as first class mail in an envelope  
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P.O. Box 1450  
Alexandria, VA 22313-1450  
on May 12, 2004

  
Martin P. Endres, Reg. No. 35,498

<u>Document Designation</u>	<u>Relevance</u>
AD U.S.P. 4,389,330	Relates to a microencapsulation process.
AE U.S.P. 4,687,777	Relates to a thiazolidinedione derivative, useful as an antidiabetic agent.
AF U.S.P. 4,839,177	Relates to a system for the controlled-rate release of active substances.
AG U.S.P. 4,891,223	Relates to a controlled release delivery coating formulation for bioactive substances.
AH U.S.P. 4,968,507	Relates to a controlled porosity osmotic pump.
AI U.S.P. 5,294,770	Relates to a laser tablet treatment system.
AJ U.S.P. 5,356,913	Relates to the use of insulin sensitizing agents to treat hypertension.
AK U.S.P. 5,376,771	Relates to a high speed process for preparing orifices in pharmaceutical dosage forms.
AL U.S.P. 5,478,852	Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of impaired glucose tolerance in order to prevent or delay the onset of noninsulin-dependent diabetes mellitus.
AM U.S.P. 5,602,133	Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of disease states at risk for progressing to noninsulin-dependent diabetes mellitus.
AN U.S.P. 5,658,474	Relates to a method and apparatus for forming dispenser delivery ports.
AO U.S.P. 5,681,584	Relates to a controlled release drug delivery device.
AP U.S.P. 5,698,220	Relates to an asymmetric membrane for use in drug delivery devices.
AQ U.S.P. 5,719,188	Relates to the use of insulin sensitizing agents to treat hypertension.
AR U.S.P. 5,859,037	Relates to sulfonylurea-glitazone combinations for diabetes.

AS U.S.P. 5,916,584	Relates to a controlled release container with a core and an outer shell.
AT U.S.P. 5,952,356	Relates to a pharmaceutical composition containing an insulin sensitivity enhancer in combination with an antidiabetic agent.
AU U.S.P. 5,955,106	Relates to a pharmaceutical preparation containing metformin and a process for producing it.
AV U.S.P. 6,011,049	Relates to drug combinations for treating diabetes containing a glitazone, a biguanide and a sulfonylurea.
AW U.S.P. 6,031,004	Relates to salts of metformin.
AX U.S.P. 6,099,859	Relates to a controlled release oral tablet having a unitary core.
AY U.S.P. 6,153,632	Relates to a method and composition for the treatment of diabetes.
AZ U.S.P. 6,191,162	Relates to a method of reducing serum glucose levels.
BA U.S.P. 6,248,363	Relates to a solid carrier for improved delivery of active ingredients in pharmaceutical compositions.
BB U.S.P. 6,291,495	Relates to a method and composition for the treatment of diabetes.
BC U.S.P. 6,296,874	Relates to a core formulation comprising troglitazone and a biguanide.
BD U.S.P. 6,329,403	Relates to a pharmaceutical composition for the treatment of diabetes.
BE U.S.P. 6,383,471	Relates to a composition and method for improved delivery of ionizable hydrophobic therapeutic agents.
BF U.S.P. 6,403,121	Relates to a modulating formulation comprising pioglitazone and metformin.
BG U.S.P. 6,451,342	Relates to a formulation containing troglitazone and metformin.
BH U.S.P. 6,475,521	Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals such as metformin.

BI U.S.P. 6,524,621	Relates to a formulation containing metformin and pioglitazone.
BJ U.S.P. 6,599,284	Relates to an osmotic device having a preformed passageway that increases in size.
BK US 2002/0071866	Relates to a dosage form having a barrier layer to laser ablation.
BL US 2003/0113371	Relates to a composition and method for maintaining blood glucose level by employing a hydrophilic matrix based oral controlled release antidiabetic composition.
BM US 2003/0118647	Relates to an extended release tablet of metformin.
BN US 2003/0118649	Relates to a drug delivery device.
CA WO 96/09823	Relates to a hypoglycemic agent from cryptolepis.
CB WO 98/11879	Relates to a gastric-retentive, oral drug dosage form for the controlled-release of sparingly soluble drugs and insoluble matter.
CC WO 98/55107	Relates to a gastric-retentive oral drug dosage form for controlled release of highly soluble drugs, including metformin.
CD WO 99/47128	Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals, including metformin.
CE WO 99/55320	Relates to an oral formulation comprising a biguanide and an organic acid.
CF WO 00/28989	Relates to a pharmaceutical composition for modified release of an insulin sensitizer and another antidiabetic agent.
CG WO 00/72827	Relates to porous drug matrices and methods of manufacture thereof.
CH WO 01/35940	Relates to a composition comprising a thiazolidinedione, metformin hydrochloride and a pharmaceutically acceptable carrier.
CI WO 01/35941	Relates to a composition comprising a thiazolidinedione, metformin hydrochloride and a pharmaceutically acceptable carrier.

CJ WO 01/82875	Relates to a core formulation comprising pioglitazone and a biguanide.
CK WO 02/28181	Relates to a sustained release pharmaceutical composition containing metformin and a method for its production.
CL WO 03/004009	Relates to a pharmaceutical composition containing metformin.
CM WO 03/35029	Relates to a formulation of an erodible, gastric retentive oral dosage form using in vitro disintegration test data.
CN WO 03/047529	Relates to an extended release pharmaceutical tablet of metformin.
CO EP 0 169 105	Relates to a controlled porosity osmotic pump.
CP EP 0 283 369	Relates to a metformin dosage formulation.
CQ EP 0 381 181	Relates to a system for the controlled release of active agents and a process for its preparation.
CR EP 0 749 751	Relates to a pharmaceutical composition for use in treatment of diabetes.
CS EP 0 753 298	Relates to a synergistic combination comprising an insulin sensitizer and a HMG-CoA reductase inhibitor for treating arteriosclerosis.
CT EP 0 781 129	Relates to a pharmaceutical preparation containing metformin and a process for producing it.
DA P. Karttunen et al. International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid- release and a sustained-release preparation" Vol. 21 No. 1 – 1983, pp. 31-36.	Relates to a sustained release metformin dosage form.

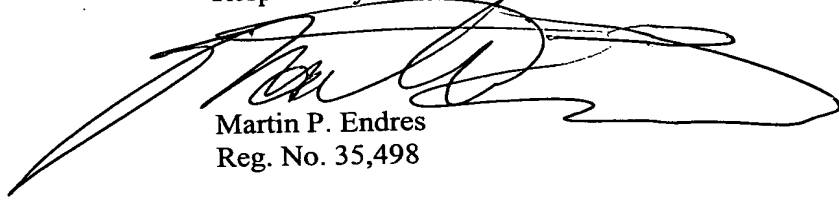
- DB Relates to a sustained release metformin dosage form.  
P.J. Pentikainen  
International Journal of Clinical  
Pharmacology, Therapy and Toxicology,  
“Bioavailability of metformin. Comparison  
of solution, rapidly dissolving tablet, and  
three sustained release products”  
Vol. 24 No. 4 – 1986, pp. 213-220
- DC Relates to a sustained release metformin dosage form.  
Finnish Monograph of the Diormin®  
Retard table with English translation
- DD Relates to metformin dosage form.  
O.J. Lucis, MD, Ph. D., MSC  
Canada Medical Association J.  
Pharmacologic Update  
“The status of metformin  
in Canada” Vol. 128  
January 1, 1983 pgs. 24-26
- DE Relates to pioglitazone.  
G. Belcher and D.R. Matthews  
Experiment and Clinical  
Endocrinology & Diabetes  
“Safety and tolerability  
of pioglitazone” Suppl 2  
(2000) pgs. 267-273
- DF Relates to a pioglitazone and metformin dosage forms.  
Daniel Einhorn, MD et al.  
Clinical Therapeutics  
“Pioglitazone Hydrochloride in  
Combination with Metformin in  
the Treatment of Type 2 Diabetes  
Mellitus: A Randomized, Placebo-  
Controlled Study”,  
Vol. 22 No. 12, 2000 pgs. 1395-1413
- DG Relate to pioglitazone.  
National Institute for Clinical Excellence  
Technology Appraisal Guidance – No. 21  
“Guidance on the Use of Pioglitazone for  
Type 2 Diabetes Mellitus”  
March 2001, pgs. 1-13

- DH Relates to pioglitazone.  
The Pharmaceutical Journal  
Vol. 265, No. 7122, p. 710  
November 11, 2000 Clinical  
(abstract only)
- DI Relates to a metformin extended-release tablet.  
Product Labeling for  
Glucophage® XR (July 2002)
- DJ Relates to combination therapy with pioglitazone and insulin in  
ADA Professional Section patients with Type 2 diabetes.  
Member Supplement  
0474 and 0503-506 (Poster)  
p. A110; A117
- DK Relates to an insulin-sensitizing diabetes agent.  
Website [www.findarticles.com](http://www.findarticles.com)  
Clinician Reviews  
"Insulin-Sensitizing Diabetes Agent"  
September 1999
- DL Relates to pioglitazone dosage formulation.  
ACTOS® product label  
Physician's Desk Reference  
55<sup>TH</sup> Edition, pp. 3171-3175
- DM Relates to Mediabet which is a tablet containing metformin.  
Rote Liste No. 11081 the Medicament  
MEDIABET of Medice; GLUCOBAY  
of Bayer and GLUCOTARD of Boehringer  
Mannheim, Chem.-Pharm. Fabrik Pütter  
GmbH & Co. KG, Kuhlweg 37-39  
Iserlohn/Germany, Editio Cantor Verlag  
für Medizin und Naturwissenschaften GmbH, 1993.
- DN Relates to a metformin dosage formulation.  
Abdallah et al.,  
Preparation and Evaluation of  
Metformin Hydrochloride  
Controlled-Release Tablets STP  
Pharma 4(1) pp. 15-20, 1988

In accordance with current Patent and Trademark Office practice no copy of the above listed United States Patents are filed herewith as well as copies of abstracts in English. Full text copies of all non-United States Patent prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made or record therein. It is believed that no fee is required for submission of this Information Disclosure Statement under 37 C.F.R. §1.97(b). However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'Martin P. Endres', is written over the typed name and registration number.

Martin P. Endres  
Reg. No. 35,498

MAILING ADDRESS:  
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PTO/SB/08A (10-01)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
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English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>													
Sheet <b>2</b> of <b>5</b>		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/777,542</td> </tr> <tr> <td>Filing Date</td> <td>February 12, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Unchalee Kositprapa</td> </tr> <tr> <td>Art Unit</td> <td></td> </tr> <tr> <td>Examiner Name</td> <td></td> </tr> <tr> <td>Attorney Docket Number</td> <td>141-446</td> </tr> </table>		Application Number	10/777,542	Filing Date	February 12, 2004	First Named Inventor	Unchalee Kositprapa	Art Unit		Examiner Name		Attorney Docket Number	141-446
Application Number	10/777,542														
Filing Date	February 12, 2004														
First Named Inventor	Unchalee Kositprapa														
Art Unit															
Examiner Name															
Attorney Docket Number	141-446														

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	AU	US- 5,955,106	09-21-1999	Moockel et al.	
	AV	US- 6,011,049	01-04-2000	Whitcomb	
	AW	US- 6,031,004	02-29-2000	Timmins et al.	
	AX	US- 6,099,859	08-08-2000	Cheng et al.	
	AY	US- 6,153,632	11-28-2000	Rieveley	
	AZ	US- 6,191,162	02-20-2001	Byrd et al.	
	BA	US- 6,248,363	06-19-2001	Patel et al.	
	BB	US- 6,291,495	09-18-2001	Rieveley	
	BC	US- 6,296,874	10-02-2001	Cutie et al.	
	BD	US- 6,329,403	12-11-2001	Odaka et al.	
	BE	US- 6,383,471	05-07-2002	Chen et al.	
	BF	US- 6,403,121	06-11-2002	Adjei et al.	
	BG	US- 6,451,342	09-17-2002	Adjei et al.	
	BH	US- 6,475,521	11-05-2002	Timmins et al.	
	BI	US- 6,524,621	02-25-2003	Adjei et al.	
	BJ	US- 6,599,284	07-29-2003	Faour	
	BK	US- 2002/0071866	06-13-2002	Geerke	
	BL	US- 2003/0113371	06-19-2003	Dhawan et al.	
	BM	US- 2003/0118647	06-26-2003	Seth	
	BN	US- 2003/011864	06-26-2003	Gao et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	CA	WO 96/09823	04-04-1996	Luo et al.		
	CB	WO 98/11879	03-26-1998	Shell et al.		
	CC	WO 98/55107	12-10-1998	Shell et al.		
	CD	WO 99/47128	09-23-1999	Timmins et al.		
	CE	WO 99/55320	11-04-1999	Nishii et al.		
	CF	WO 00/28989	05-25-2000	Lewis et al.		
	CG	WO 00/72827	12-07-2000	Straub et al.		
	CH	WO 01/35940	05-25-2001	Lewis et al.		
	CI	WO 01/35941	05-25-2001	Lilliot et al.		
	CJ	WO 01/82875	11-08-2001	Cutie et al.		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet 3 of 5

**Complete if Known**

Application Number	10/777,542
Filing Date	February 12, 2004
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-446

[illegible]

Examiner Initials <sup>2</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	CK	WO 02/28181	04-11-2002	Gidwani et al.		
	CL	WO 03/004009	01-16-2003	Matharu et al.		
	CM	WO 03/035029	05-01-2003	Louie-Helm et al.		
	CN	WO 03/047529	06-12-2003	Seth et al.		
	CO	EP 0 169 105	01-22-1986	Zentner et al.		
	CP	EP 0 283 369	09-21-1988	Wiernsperger et al.		
	CO	EP 0 381 181	08-08-1995	Wenzel et al.		
	CR	EP 0 749 751	12-27-1996	Ikeda et al.		
	CS	EP 0 753 298	11-21-2001	Tsujita et al.		
	CT	EP 0 781 129	07-02-1997	Moeckel et al.		

**Examiner  
Signature**

Date  
Considered

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/777,542
		Filing Date	February 12, 2004
		First Named Inventor	Unchalee Kositprapa
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	141-446
Sheet	4	of	5

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.	
	DB	P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving tablet, and three sustained-release products", Vol. 24, No. 4 - 1986, pp. 213-220.	
	DC	Finnish Monograph of the Diformin®, Retard tablet, with English translation	
	DD	O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.	
	DE	G. Belcher and D.R. Matthews, Experiment and Clinical Endocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.	
	DF	Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.	
	DG	National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.	
	DH	The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).	

Examiner Signature	Date Considered
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		First Named Inventor	Unchalee Kositprapa
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	141-446
Sheet	5	of	5

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	DI	Product Labeling for Glucophage® XR (July 2002).	
	DJ	ADA Professional Section Member Supplement 0474 and 0503-506 (Poster) p. A110; A117	
	DK	Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999.	
	DL	ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175	
	DM	Rote Liste No. 11081 the Medicament MEDIABET of Medice; GLUCOBAY of Bayer; and GLUCOTARD of Boehringer Mannheim, Chem.-Pharm. Fabrik Pütter GmbH & Co. KG, Kuhlweg 37-39 Iserlohn/Germany, Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	
	DN	Abdallah et al., "Preparation and Evaluation of Metformin Hydrochloride Controlled-Release Tablets" STP Pharma 4(1) pp. 15-20, 1988.	

Examiner Signature	Date Considered
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